

Application No. 10/084,491  
Amendment under 37 CFR 1.116  
Reply to Office Action dated November 5, 2003  
March 5, 2004

REMARKS

By this amendment, claims 2, 3 and 7 have been amended and new claims 12-15 have been added to this application. Currently, claims 2-15 are pending in the application with claims 4, 10-11 currently being withdrawn from consideration.

Applicant respectfully requests that the Examiner to withdraw the finality of the Office Action dated November 5, 2003 for the following reasons. Applicant submitted a Request for Reconsideration on June 2, 2003. The Examiner agreed that the previous final rejection was improper and issued a new office action dated November 5, 2003, which was then made final.

Applicant's Request for Reconsideration did not amend any of the pending claims. Therefore, applicant believes that any new rejection based on newly cited prior art should have been made in a non-final office action. According to MPEP 706.07(d), "If, on request by applicant for reconsideration, the primary examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection." Therefore, since the Examiner granted applicant's Request for Reconsideration, the current Office Action should have been a non-final Office Action.

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Accordingly, applicant respectfully requests that the finality of previous Office Action be withdrawn and the currently amended claims be examined on their merits and allowed.

Claims 2-3 and 5-9 were rejected under 35 USC 102(b) as being anticipated by Fabozzi (U.S. Patent No. 5,498,241). Claims 2-3 and 5-9 were rejected under 35 USC 102(b) as being anticipated by Shaw (U.S. Patent No. 5,779,679). Claims 2-3 and 5-9 were rejected under 35 USC 102(b) as being anticipated by Brimhall (U.S. Patent No. 5,676,656).

These rejections are respectfully traversed in view of the amendments to the claims and the following remarks.

The present invention relates to a safety indwelling syringe which allows safe disposal of a hollow needle after use and more particularly to a safety indwelling syringe which allows safe disposal of a hollow needle by pulling out a portion of its sheath in an easy operation.

According to the elected embodiment, the fixed sheath 3 is a tube and it is formed with a slit 3a in the vicinity of its distal end as shown in Fig. 2. The slit 3a communicates with a front end opening 3b of the fixed sheath 3 for slidably accommodating a proximal portion of a second wing 5b coupled to

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the protective sheath 4. The end of the slit prevents further movement of the fixed sheath 3 relative to the protective sheath 4.

A locking means 7 is provided at a front end of the fixed sheath 3 and a proximal end of the protective sheath 4 for preventing the protective sheath 4 from separating. The locking means 7 consists of a locking slot 7a and a guide surface 7c of a tapered surface provided in the fixed sheath 3 and a locking projection 7b protruding from an outer periphery of the protective sheath 4 to be fitted into the locking slot 7a.

The protective sheath 4 is similar to the fixed sheath 3, a tube with opposite opening ends and is designed to cover the hollow needle 1 when pulled out forwardly from the fixed sheath 3 and locked.

The safety indwelling syringe of this invention is supplied with the hollow needle 1 covered by the protective sheath 4 as shown in Fig. 4. In use, the hollow needle 1 is exposed as shown in Fig. 5 to be inserted into the body of a patient with the wings 5 held by an operator. After use, the second wing 5b is slid by the operator to slide the protective sheath 4 forwardly or toward the tip of the hollow needle 1, housing the hollow

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needle 1 in the protective sheath 4, thereby enabling safe disposal without touching the body of the hollow needle 1.

Claim 7 has been amended to recite that the safety indwelling syringe comprises "a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath".

Fabozzi relates to an intravenous infusion set and in particular, to a winged needle assembly usable for venipuncture that includes an integral protective member to reduce accidental needle stick from such infusion sets. Fabozzi discloses that the infusion set 10 includes a winged needle assembly 12, a section of hollow medical tubing 14, a standard fluid connector 16 and a removable sheath 18 covering the needle as shown in Fig. 2.

Fabozzi also discloses that the wing 62 integral with the hollow tubular member 42 is pressed against the skin and the wing 36 integral with the hub is rotated into alignment with the longitudinal slot 52 as shown in Fig. 5. The tapered lead-in portion 58 at the front end of the slot 52 facilitates alignment and entry of the wing 36 or stem portion of the wing 36 into the

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slot. The medical tubing 14 connected to the winged needle assembly 12 is pulled back, which pulls the wing 36 or stem portion 38 through the slot 52 and withdraws the needle 22 from the vein and into the hollow tubular protective member 42.

Fabozzi also discloses that when the wing or step portion 38 reaches the lateral notch 60 at the lock-out position of the slot, the wing or stem automatically disengages from the slot. The resiliency of the plastic material of the partially split tubular member 42 causes of the slot 52 to substantially close on itself as seen at the lock-out position 56 in Fig. 6.

Fabozzi does not disclose a protective sheath that is slidably movable and guided by the tubular portion of the fixed sheath, between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath.

Applicant believes that in Fabozzi, the sheath 18 is removable and does not move inside the fixed sheath. Also, Fabozzi does not disclose two positions for the protective sheath where in one position, the protective sheath covers the needle and in the other position, the protective sheath is disposed

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inside the fixed sheath. Also, when the needle is moved inside the other sheath in Fabozzi, the entire connected section moves out the back end of the outer sheath. This does not happen in the present invention.

It is therefore submitted that claims 2-3 and 5-9 are allowable over Fabozzi and this rejection should be withdrawn.

Shaw relates to a medical device designed to insert and maintain in place an IV and to allow for retraction of the needle in the removal process to significantly decrease the possibility of inadvertent needle sticks into the patient or health care workers.

Shaw discloses in Fig. 1, a device body 12, a needle holder 14, a spring 15 and a needle 16 which extends from needle holder 14 and has a sharpened tip 17. The device body 12 has a pair of holding wings 18 and a pair of retraction wings 20. Shaw also discloses that the needle holder 14 has opposing arms 38 each of which terminate in a lug 40. Lugs 40 are used to position and maintain (or lock) needle holder 14 in each of its two positions (extended and retracted) of the preferred embodiment.

Shaw also discloses in Fig. 2, the needle holder 14 in the retracted position. Needle 16 is entirely contained within

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device body 12. Spring 15 is in a less compressed state. Spring 15 must be positioned and sized such that sufficient biasing force to slide needle holder 14 will continue at least until lugs 40 move completely behind shoulders 46.

Shaw does not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath.

It is therefore submitted that claims 2-3 and 5-9 are allowable over Shaw and this rejection should be withdrawn.

Brimhall relates to an introducer needle assembly for an intravenous catheter this is used for directing fluid into or withdrawing fluid from a patient.

Brimhall discloses that when needle 40 is inserted completely into catheter 20, the distal tip of needle 40 extends beyond the distal tip of catheter 20 as shown in Fig. 2. In addition, the distal end of fin 31 extends beyond the distal end of squeeze grips 25 as shown in Fig. 2. In this arrangement, catheter and introducer needle assembly 10 is ready for insertion into a patient. The healthcare worker squeezes squeeze grips 25

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and thus maintains the relative axial position of needle 40 with respect to catheter 20.

Brimhall also discloses in Figs. 5 and 6, that by shielding the distal tip of needle 40 inside catheter 20, catheter 20 can be advanced into the vein without the needle 40 puncturing the vein again. Needle 40 provides column strength to catheter 20 as it is advanced into the vein. Needle 40 can be removed from catheter hub 21 leaving catheter 20 in place in the patient.

Brimhall does not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath, between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath.

It is therefore submitted that claims 2-3 and 5-9 are allowable over Brimhall and this rejection should be withdrawn.

New dependent claim 12 has been added tot his application and depends from independent claim 7. New dependent claim 12 recites "wherein the fixed sheath includes a slit and the protective sheath includes a wing coupled thereto, the wing being movable along the slit until a portion of the wing contacts an end of the slit and stops further movement of the wing, and



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wherein the end of the slit and the locking means restrict sliding movement of the protective sheath in both directions". This feature is not shown or suggested in the prior art of record.

Also, new independent claim 13 and new dependent claims 14 and 15 dependent from new independent claim 13 have been added to this application. New independent claim 13 recites "the fixed sheath and the protective sheath comprising locking means having a slot and a latch projection for engaging with the slot so that the locking means prevents the protective sheath from separating from the fixed sheath". New dependent claim 14 recites "wherein the fixed sheath includes a slit and the protective sheath includes a wing coupled thereto, the wing being movable along the slit until a portion of the wing contacts an end of the slit and stops further movement of the wing, and wherein the end of the slit and the locking means restrict sliding movement of the protective sheath in both directions". New dependent claim 15 recites "a safety indwelling syringe as set forth in claim 13, wherein the protective sheath comprises at least two slide sheaths". Dependent claim 15 is similar to withdrawn claim 4.

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Applicant respectfully submits that these new claims recite additional features that also define over the prior art of record. Allowance of these claims is also respectfully requested.

In view of foregoing claim amendments and remarks, it is respectfully submitted that the application is now in condition for allowance and an action to this effect is respectfully requested.

If there are any questions or concerns regarding the claim amendments or these remarks, the Examiner is requested to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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